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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,000	11/28/2000	Anthony J. Polverino	MBHB00-450-A	6633

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EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/724,000	POLVERINO ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,13,14,16,46,47,57 and 59-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9, 13, 14, 16, 46, 47, 57, and 59-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 November 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20070501*.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed March 29, 2007, has been entered. Claims 9, 13, 14, 16, 46, 47, 57, and 61 have been amended.

2. The declaration under 37 C.F.R. § 1.131 by Anthony J. Polverino and Roland Luethy, which was filed March 29, 2007, is acknowledged and has been entered.

3. Claims 9, 13, 14, 16, 46, 47, 57, and 59-61 are pending in the application.

Response to Declaration under 37 C.F.R. § 1.131

4. The declaration under 37 C.F.R. § 1.131 by Anthony J. Polverino and Roland Luethy, which was filed March 29, 2007, has been carefully considered but is ineffective to overcome the rejections of claims 9, 13, 14, 16, 46, 47, 57, and 59-61 under 35 U.S.C. 102(e) and claims 14, 57, and 59-61 under 35 U.S.C. 103(a) as being anticipated by, or unpatentable over U.S. Patent Application Publication No. 2002/0068319 A1.

The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of U.S. Patent Application Publication No. 2002/0068319 A1 to either a constructive reduction to practice or an actual reduction to practice.

Claims 9, 13, and 57 are directed to a polypeptide comprising the amino acid sequence of SEQ ID NO: 5.

The declaration states the invention, disclosed and claimed in this application, was conceived and reduced to practice in the United States by Applicant before September 24, 1999, but the only evidence of such is a submission depicting the sequence of a nucleic acid molecule. Although it appears the depicted polynucleotide sequence is the same as the sequence listed in the instant Sequence Listing as SEQ ID NO: 4, there is no indication that this sequence encodes the claimed invention (i.e., a polypeptide comprising the amino acid sequence of SEQ ID NO: 5). Furthermore, although it appears that there may be an open reading frame, initiating with the first codon encoding methionine (i.e., the sequence ATG at positions 29-31 of that sequence), which may encode the entirety of the amino acid sequence of SEQ ID NO: 5, the declaration

fails to state that it was recognized, prior to September 24, 1999, that this open reading frame of the depicted evidentiary sequence encodes a polypeptide having the amino acid sequence set forth in the instant application as SEQ ID NO: 5.

Notably, upon mere superficial examination of the evidentiary sequence, there are a plurality of putative initiation codons that might be utilized to encode structurally disparate proteins; so it is conceivable that a nucleic acid molecule comprising the depicted sequence might not encode a polypeptide comprising the amino acid sequence of SEQ ID NO: 5, but may instead encode a polypeptide having a different amino acid sequence. Furthermore, there is a possibility that the sequence depicted in the evidentiary submission may encode more than one polypeptide, if, for example, more than one reading frame could be utilized. Apparently lacking therefore in the declaration is any reasonably conclusive indication that this sequence encodes the claimed polypeptide comprising the amino acid sequence of SEQ ID NO: 5, and no other.

With further regard to claim 13, which is drawn in the alternative to a polypeptide comprising the amino acid sequence encoded by a DNA insert encoding a "Secs-1 polypeptide"[1], it is aptly noted that the claimed polypeptide does not necessarily comprise the disclosed amino acid sequence of SEQ ID NO: 5. Rather, the claims encompasses *any* polypeptide encoded by nucleic acid molecule comprising a nucleic acid sequence of a DNA insert encoding a "Secs-1 polypeptide", where said DNA insert is contained in a deposited material having the ATCC accession number PTA-1755. However, because it is unclear if the polynucleotide sequence of the DNA insert is identical to the polynucleotide sequence listed in this application as SEQ ID NO: 4, it is also unclear if the sequence of the DNA insert is identical to the polynucleotide sequence submitted as evidence with the declaration. Additionally, it is unclear that the DNA insert to which the claim is directed encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 5 because the claim recites, "wherein the nucleic acid molecule encodes a polypeptide of the amino acid sequence set forth in SEQ ID NO: 5". As further noted in the

[1] At page 11, lines 4-11, the specification discloses: "The term 'Secs-1 polypeptide' refers to a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 or SEQ ID NO: 5, and related polypeptides. Related polypeptides include: Secs-1 polypeptide allelic variants, Secs-1 polypeptide orthologs, Secs-1 polypeptide splice variants, Secs-1 polypeptide variants, and Secs-1 polypeptide derivatives, which possess at least one activity of the polypeptide as set forth in SEQ ID NO: 2 or SEQ ID NO: 5. Secs-1 polypeptides may be mature polypeptides, as defined herein, and may or may not have an amino terminal methionine residue, depending on the method by which they are prepared."

rejection of claim 13 under 35 U.S.C. § 112, second paragraph, which is set forth below, it cannot be determined to which nucleic acid molecule the claim refers, or whether this nucleic acid molecule is, or is not, the DNA insert; nevertheless, because there are a plurality of polypeptides *of* the amino acid sequence set forth in SEQ ID NO: 5, it is not apparent that the nucleic acid molecule necessarily encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 5, as it may instead comprise any portion thereof. Finally, because the DNA insert to which the claim is directed comprises a plurality of nucleotide sequences, and the claim is directed to a polypeptide encoded by a nucleic acid molecule comprising a nucleotide sequence of the DNA insert, it is presumed that the claim encompasses a plurality of structurally and/or functionally disparate polypeptides encoded by the any of such different species of nucleic acid molecules. Thus, while it is not immediately apparent that the evidence provided with the declaration establishes either a constructive reduction to practice or an actual reduction to practice of the claimed polypeptide comprising the amino acid sequence of SEQ ID NO: 5, the evidence is not commensurate with the breadth of claim 13, which encompasses polypeptide comprising mere portions of the amino acid sequence of SEQ ID NO: 5.

Claim 16 is similarly more broadly directed, in the alternative, to *any* polypeptide encoded by a nucleic acid molecule comprising a nucleotide sequence as set forth in SEQ ID NO: 4, a nucleic acid sequence of a DNA insert encoding a "Secs-1 polypeptide", or a nucleic acid sequence encoding a polypeptide having the amino acid sequence as set forth in SEQ ID NO: 5 – not necessarily a polypeptide comprising the amino acid sequence of SEQ ID NO: 5.

Insofar as claim 16 is directed, in the alternative, to *any* polypeptide encoded by a nucleic acid molecule comprising a nucleotide sequence as set forth in SEQ ID NO: 4. Again, the claimed polypeptide need not comprise the amino acid sequence of SEQ ID NO: 5, though it is necessarily encoded by a nucleic acid molecule comprising a nucleotide sequence of SEQ ID NO: 4. The portion of the nucleic acid molecule comprising a nucleotide sequence of SEQ ID NO: 4, which encodes the claimed polypeptide is not necessarily, that portion comprising a nucleotide sequence of SEQ ID NO: 4; so the claimed polypeptide may comprise an amino acid sequence that is wholly different from the disclosed amino acid sequence of SEQ ID NO: 5.

Furthermore, SEQ ID NO: 4 comprises a plurality of nucleic acid sequences[2]. Therefore, the claim is directed to a nucleic acid molecule comprising any 2 or more nucleotides of SEQ ID NO: 4, which presumably encode a large plurality of polypeptides having substantially varying structures and functions, and no structural or functional relationship to the disclosed polypeptide comprising SEQ ID NO: 5. Despite the fact that it is not immediately apparent that the sequence depicted in the evidentiary submission encodes a polypeptide comprising SEQ ID NO: 5, it fails to show either a constructive reduction to practice or an actual reduction to practice of such a genus of structurally and/or functionally disparate polypeptides.

Insofar as claim 16 is directed, in the alternative, to *any* polypeptide encoded by nucleic acid molecule comprising a nucleic acid sequence of a DNA insert encoding a "Secs-1 polypeptide", where said DNA insert is contained in a deposited material having the ATCC accession number PTA-1755, it is unclear if the polynucleotide sequence of the DNA insert is identical to the polynucleotide sequence listed in this application as SEQ ID NO: 4, and so it is unclear if the sequence of the DNA insert is identical to the polynucleotide sequence submitted as evidence with the declaration. Moreover, it is unclear that the DNA insert to which the claim is directed encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 5 because the claim recites, "wherein the nucleic acid molecule encodes a polypeptide of the amino acid sequence set forth in SEQ ID NO: 5". As further noted in the rejection of claim 16 under 35 U.S.C. § 112, second paragraph, which is set forth below, it cannot be determined to which nucleic acid molecule the claim refers, or whether this nucleic acid molecule is, or is not, the DNA insert; nevertheless, because there are a plurality of polypeptides *of* the amino acid sequence set forth in SEQ ID NO: 5, it is not apparent that the nucleic acid molecule necessarily encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 5, as it may instead comprise any portion thereof. Finally, because the DNA insert to which the claim is directed comprises a plurality of nucleotide sequences, and the claim is directed to a polypeptide encoded by a nucleic acid molecule comprising a nucleotide sequence of the DNA insert, it is presumed that the claim encompasses a plurality of structurally and/or functionally disparate polypeptides encoded by the any of such different species of nucleic acid molecules. Thus, while it is not

[2] A "nucleotide sequence" of SEQ ID NO: 4 is interpreted to mean any two or more contiguous

immediately apparent that the evidence provided with the declaration establishes either a constructive reduction to practice or an actual reduction to practice of the claimed polypeptide comprising the amino acid sequence of SEQ ID NO: 5, the evidence is not commensurate with the breadth of claim 16, which encompasses polypeptide comprising mere portions of the amino acid sequence of SEQ ID NO: 5.

Insofar as claim 16 is directed, in the alternative, to *any* polypeptide encoded by a nucleic acid molecule comprising a nucleic acid sequence encoding a polypeptide having the amino acid sequence as set forth in SEQ ID NO: 5, the claimed polypeptide need not comprise the recited amino acid sequence. Inasmuch as there are a plurality of nucleic acid molecules comprising a nucleotide sequence encoding a polypeptide having the amino acid sequence as set forth in SEQ ID NO: 5, the claims are directed to a plurality of polypeptides. The nucleic acid molecule encoding the claimed polypeptide, i.e., a nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide having the amino acid sequence as set forth in SEQ ID NO: 5 does not necessarily encode such a polypeptide; it may encode another polypeptide, which may or may not the amino acid sequence of SEQ ID NO: 5, but might instead comprise the amino acid sequence encoded by a different reading frame, or perhaps a polypeptide comprising only a portion of the amino acid sequence of SEQ ID NO: 5. Again, apparently lacking in the declaration is any reasonably conclusive indication that the sequence depicted in the evidentiary submission encodes the claimed polypeptide comprising the amino acid sequence of SEQ ID NO: 5, and no other, but nonetheless, were the claims properly given the broadest, reasonable interpretation that is both consistent with the specification, as well as that which would be understood by the artisan, the evidence presented with declaration could not be deemed commensurate with the breadth of claim 16, which is not so limited, presumably encompasses a genus of structurally and/or functionally disparate polypeptides.

Claim 61 is drawn to a polypeptide encoded by a nucleic acid molecule encoding a polypeptide of the amino acid sequence set forth in SEQ ID NO: 5. However, the claimed polypeptide need not *consist of* an amino acid sequence of SEQ ID NO: 5[3]; and moreover, the

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nucleotides of SEQ ID NO: 4.

[3] A polypeptide of the amino acid sequence set forth in SEQ ID NO: 5 is interpreted to mean a polypeptide comprising any two or more contiguous amino acids of SEQ ID NO: 5.

claimed polypeptide does not necessarily comprise SEQ ID NO: 5, though it must be encoded by a nucleic acid molecule comprising a nucleotide sequence of a region of the nucleotide sequence of SEQ ID NO: 4 or alternatively a DNA insert encoding a "Secs-1 polypeptide". The portion of the nucleic acid molecule comprising a nucleotide sequence of a region of the nucleotide sequence of SEQ ID NO: 4 or alternatively a DNA insert encoding a "Secs-1 polypeptide", which encoded the claimed polypeptide, is not necessarily the portion comprising a nucleotide sequence of a region of the nucleotide sequence of SEQ ID NO: 4 or alternatively a DNA insert encoding a "Secs-1 polypeptide". As such, the claimed polypeptide may comprise an amino acid sequence that is wholly different from the disclosed amino acid sequence of SEQ ID NO: 5. Furthermore, SEQ ID NO: 4 comprises a plurality of "regions" comprising a plurality of nucleic acid sequences[4]. Similarly, the DNA insert to which the claim is directed presumably comprises a plurality of "regions" comprising a plurality of nucleic acid sequences. Therefore, the claim is directed to a nucleic acid molecule comprising any 2 or more nucleotides of SEQ ID NO: 4 or the DNA insert, which presumably encode a large plurality of polypeptides having substantially varying structures and functions, and no structural or functional relationship to the disclosed polypeptide comprising SEQ ID NO: 5. So, despite the fact that it is not immediately apparent that the sequence depicted in the evidentiary submission encodes a polypeptide comprising SEQ ID NO: 5, it fails to show either a constructive reduction to practice or an actual reduction to practice of such a genus of structurally and/or functionally disparate polypeptides.

Then, with regard to claim 14, which is directed to a polypeptide comprising the amino acid sequence of SEQ ID NO: 6, optionally further comprising an amino-terminal methionine, the evidence submitted is insufficient to establish a conception of the invention prior to the effective date of U.S. Patent Application Publication No. 2002/0068319 A1. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). As noted above, the declaration states that the invention disclosed and claimed in this application

[4] Again, a "nucleotide sequence" of SEQ ID NO: 4 is interpreted to mean any two or more contiguous

was conceived and reduced to practice in the United States by Applicant before September 24, 1999, but the only evidence of such is the sequence of a nucleic acid molecule comprising a polynucleotide sequence that appears to be the same as the sequence listed in the instant Sequence Listing as SEQ ID NO: 4. It is however not apparent that this polynucleotide sequence would be immediately recognized as encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 6, which might further comprise an amino-terminal methionine.

Grounds of Rejection Withdrawn

5. Unless specifically reiterated below, Applicant's amendment and/or arguments filed March 29, 2007, have obviated or rendered moot the grounds of objection and rejection set forth in the previous Office action mailed March 29, 2006.

Priority

6. Applicant's claim under 35 U.S.C. §§ 119 and/or 120 for benefit of the earlier filing date of Application 09/599,087, filed June 21, 2000, is acknowledged.

However, claims 13, 14, 16, 46, 47, 57, and 59-61 do not properly benefit under §§ 119 and/or 120 by the earlier filing dates of the priority documents claimed, since those claims are rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description and a sufficiently enabling disclosure.

To receive benefit of the earlier filing date under §§ 119 and/or 120, the later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Accordingly, the effective filing date of claims 13, 14, 16, 46, 47, 57, and 59-61 is deemed the filing date of the instant application, namely November 28, 2000.

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nucleotides of SEQ ID NO: 4.

Grounds of Rejection

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 13, 16, 46, and 47 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13, 16, 46, and 47 are indefinite because claims 13 and 16 recite, "the nucleic acid molecule". There is no antecedent basis for this limitation in the claims. Moreover, it cannot be determined to which nucleic acid molecule the claim refers, or whether this nucleic acid molecule is, or is not, the DNA insert. Accordingly, the claims fail to delineate the subject matter that is regarded as the invention with the requisite clarity and particularity to permit the skilled artisan to know or determine infringing subject matter, so as to satisfy the requirement set forth under 35 U.S.C. § 112, second paragraph.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. The rejection of claims 13, 14, 16, 46, 47, 57, and 59-61 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "written description" rejection.

As explained in the preceding Office action, the considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, ``Written Description" Requirement (Federal Register; Vol. 66, No. 4,

January 5, 2001). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

It is further noted that these guidelines state that rejection of a claim for lack of written description, where the claim recites the language of an original claim should be rare. Nevertheless, these guidelines further state, "the issue of a lack of written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant has possession of the claimed invention" (*Id.* at 1105). The "Guidelines" continue:

> The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. This problem may arise where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.

With further regard to the proposition that, as *original* claims, the claims themselves provide *in haec verba* support sufficient to satisfy the written description requirement, the Federal Circuit has explained that *in ipsis verbis* support for the claims in the specification does not *per se* establish compliance with the written description requirement:

> Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). *See also:* University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 1892 (CA FC 2004).

Thus, an original claim may provide written description for itself, but it must still be an adequate written description, *which establishes that the inventor was in possession of the invention.*

In this instance, claims 13, 14, 16, 46, 47, 57, and 59-61are directed to a genus of polypeptides, which is not described in the specification, as filed, with the requisite clarity and

particularity necessary to permit the skilled artisan to immediately envision, recognize or distinguish at least a substantial number of the members of this genus. Consequently, the specification, as filed, would not reasonably convey to the skilled artisan that Applicant had possession of this genus of polypeptides, as a whole, at the time the application was filed, so as to meet the written description requirement set forth under 35 U.S.C. § 112, first paragraph.

Beginning at page 5 of the amendment filed March 29, 2007, Applicant has traversed the propriety of this ground of rejection, arguing in brief that the claims, as presently amended, comply with the written description requirement.

Applicant's argument has been carefully considered but not found persuasive for the following reasons:

Claims 9, 13, and 57 are directed in part to a polypeptide comprising the amino acid sequence of SEQ ID NO: 5.

The specification describes with particularity an isolated nucleic acid molecule. This nucleic acid molecule comprises the polynucleotide sequence that is set forth in the Sequence Listing as SEQ ID NO: 4.

The specification discloses that the isolated nucleic acid molecule encodes a polypeptide having a deduced amino acid sequence corresponding to the amino acid sequence set forth as SEQ ID NO: 5, which comprises a predicted signal peptide (i.e., a leader sequence); see, e.g., Figure 2 and the brief description thereof at page 8, lines 1-3, of the specification.

The specification discloses that the presence of a predicted signal peptide at the amino-terminus of an apparently full-length polypeptide comprising the amino acid sequence of SEQ ID NO: 5 suggests the mature polypeptide is secreted. It is for this reason the polypeptide and variants thereof have been termed, "Secreted Epithelial Colon Stromal-1 (Secs-1) polypeptides"[5]; see, e.g., the abstract.

Though the specification discloses that surprisingly, Secs-1 polypeptide was differentially expressed in epithelial cells, specifically epithelial cells of the cheek, tongue, esophagus, large intestine, uterus, thymus, nipple, skin, and nasal cavity, suggesting therefore that the present polypeptide has demonstrated utility in differentiating this cell type from the background, the

[5] See Footnote #1.

specific biological function or activity of the polypeptide has not been described with any particularity.

It appears that the function of this polypeptide has yet to be fully characterized.

Nevertheless, insofar as the claims are drawn to a polypeptide comprising SEQ ID NO: 5 (e.g., claims 9, 13, and 57), because the amino acid sequence disclosed is presumed intact, it is believed the written description requirement has been met.

Then, with regard to claim 14, which is directed to a polypeptide comprising the amino acid sequence of SEQ ID NO: 6, optionally further comprising an amino-terminal methionine, the amino acid sequence of SEQ ID NO: 6 is the amino acid sequence of the mature polypeptide, which lacks the leader sequence (i.e., the secretory signal sequence of which the full-length polypeptide of SEQ ID NO: 5 is comprised). Claim 14 encompasses polypeptides comprising the amino acid sequence of SEQ ID NO: 6, though otherwise having varying structures; nonetheless, there is a reasonable presumption that the claimed polypeptides will have or retain the function a polypeptide consisting of the amino acid sequence of SEQ ID NO: 6. It is for this reason that claim 14 has not been included in this rejection.

Otherwise the claims are directed to an inadequately described genus of structurally and functionally variable polypeptides, which are encoded by one or more nucleotide sequences that comprise some common structural features but which vary at least inasmuch as the functioning sequence encoding the polypeptide is concerned.

As explained in the preceding Office actions, the sequence of the DNA insert contained by the deposited material has not been disclosed; and while the insert is described as encoding a "Secs-1 polypeptide", it is not evident that the DNA insert encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 5.

Furthermore, while Figure 2 depicts the deduced amino acid sequence (i.e., SEQ ID NO: 5) of a polypeptide that would be encoded by an open reading frame, initiating with the first codon encoding methionine (i.e., the sequence ATG at positions 29-31 of the nucleotide sequence depicted, namely SEQ ID NO: 4), upon mere superficial examination of the nucleotide sequence, there are a plurality of putative initiation codons that might be utilized to encode structurally disparate proteins. Therefore, it is conceivable that a nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 4 might not encodes a polypeptide

comprising the amino acid sequence of SEQ ID NO: 5, but may instead encode a polypeptide having a different amino acid sequence, and/or there is a possibility that the nucleotide sequence encodes more than one polypeptide. If, for example, more than one reading frame were utilized, the nucleotide sequence might encode a plurality of different polypeptides.

In contrast to claim 9, for example, which is drawn to a polypeptide comprising the amino acid sequence of SEQ ID NO: 5, claim 13 is drawn, in the alternative, to a polypeptide comprising the amino acid sequence encoded by a DNA insert encoding a "Secs-1 polypeptide". It is aptly noted that the claimed polypeptide according to claim 13 *does not necessarily comprise the disclosed amino acid sequence of SEQ ID NO: 5*. Rather, claim 13 encompasses *any* polypeptide encoded by nucleic acid molecule comprising a nucleic acid sequence of a DNA insert encoding a "Secs-1 polypeptide", where said DNA insert is contained in a deposited material having the ATCC accession number PTA-1755.

Because it is unclear if the polynucleotide sequence of the DNA insert is identical to the polynucleotide sequence listed in this application as SEQ ID NO: 4, it is also unclear if the sequence of the DNA insert is identical to the polynucleotide sequence submitted as evidence with the declaration. Additionally, it is unclear that the DNA insert to which the claim is directed encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 5 because the claim recites, "wherein the nucleic acid molecule encodes a polypeptide of the amino acid sequence set forth in SEQ ID NO: 5". As further noted in the above rejection of claim 13 under 35 U.S.C. § 112, second paragraph, it cannot be determined to which nucleic acid molecule the claim refers, or whether this nucleic acid molecule is, or is not, the DNA insert.

Nevertheless, because there are a plurality of polypeptides *of* the amino acid sequence set forth in SEQ ID NO: 5, it is not apparent that the nucleic acid molecule necessarily encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 5, as it may instead comprise any portion thereof. Finally, because the DNA insert to which the claim is directed comprises a plurality of nucleotide sequences, and the claim is directed to a polypeptide encoded by a nucleic acid molecule comprising a nucleotide sequence of the DNA insert, it is presumed that the claim encompasses a plurality of structurally and/or functionally disparate polypeptides encoded by the any of such different species of nucleic acid molecules. Thus, claim 13 encompasses a genus of polypeptides that includes members comprising mere portions of the amino acid sequence of

SEQ ID NO: 5; yet, the only member of the genus that is described with particularity is the polypeptide comprising the amino acid sequence of SEQ ID NO: 5, which is not reasonably considered representative of the claimed genus of such structurally and/or functionally disparate polypeptides.

Because the polypeptides encompassed by the claims have no particular function or activity, there is no correlation between any one particularly identifying functional feature that is shared by members of the genus and any particularly identifying (i.e., substantial) structural feature that is also common among at least most of its members; consequently, the skilled artisan could not immediately envision, recognize or distinguish at least a substantial number of the claimed polypeptides. It is for this reason that the specification would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

Applicant is reminded, "generalized language may not suffice if it does not convey the detailed identity of an invention." *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004). In this instance, there is no language that adequately describes the claimed genus of polypeptides, as a whole, with the requisite particularity to permit the skilled artisan to reasonably conclude that Applicant had possession of those polypeptides at the time the application was filed.

Claim 16 is similarly more broadly directed, in the alternative, to *any* polypeptide encoded by a nucleic acid molecule comprising a nucleotide sequence as set forth in SEQ ID NO: 4, a nucleic acid sequence of a DNA insert encoding a "Secs-1 polypeptide", or a nucleic acid sequence encoding a polypeptide having the amino acid sequence as set forth in SEQ ID NO: 5 – not necessarily a polypeptide comprising the amino acid sequence of SEQ ID NO: 5.

Insofar as claim 16 is directed, in the alternative, to *any* polypeptide encoded by a nucleic acid molecule comprising a nucleotide sequence as set forth in SEQ ID NO: 4. Again, the claimed polypeptide need not comprise the amino acid sequence of SEQ ID NO: 5, though it is necessarily encoded by a nucleic acid molecule comprising a nucleotide sequence of SEQ ID NO: 4. The portion of the nucleic acid molecule comprising a nucleotide sequence of SEQ ID NO: 4, which encodes the claimed polypeptide is not necessarily, that portion comprising a nucleotide sequence of SEQ ID NO: 4; so the claimed polypeptide may comprise an amino acid

sequence that is wholly different from the disclosed amino acid sequence of SEQ ID NO: 5. Furthermore, SEQ ID NO: 4 comprises a plurality of nucleic acid sequences[6]. Therefore, the claim is directed to a nucleic acid molecule comprising any 2 or more nucleotides of SEQ ID NO: 4, which presumably encode a large plurality of polypeptides having substantially varying structures and functions, and no structural or functional relationship to the disclosed polypeptide comprising SEQ ID NO: 5. The polypeptide comprising the amino acid sequence of SEQ ID NO: 5 is not reasonably considered representative of the claimed genus of such structurally and/or functionally disparate polypeptides.

The Federal Circuit has decided that a patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated. See *Noelle v. Lederman*, 69 USPQ2d 1508 1514 (CA FC 2004) (citing *Enzo Biochem II*, 323 F.3d at 965; *Regents*, 119 F.3d at 1568).

Insofar as claim 16 is directed, in the alternative, to *any* polypeptide encoded by nucleic acid molecule comprising a nucleic acid sequence of a DNA insert encoding a "Secs-1 polypeptide", where said DNA insert is contained in a deposited material having the ATCC accession number PTA-1755, it is unclear, as also explained above with regard to claim 13, if the polynucleotide sequence of the DNA insert is identical to the polynucleotide sequence listed in this application as SEQ ID NO: 4, and so it is unclear if the sequence of the DNA insert is identical to the polynucleotide sequence submitted as evidence with the declaration. Moreover, as also explained above, it is unclear that the DNA insert to which the claim is directed encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 5 because the claim recites, "wherein the nucleic acid molecule encodes a polypeptide of the amino acid sequence set forth in SEQ ID NO: 5". As further noted in the above rejection of claim 16 under 35 U.S.C. § 112, second paragraph, it cannot be determined to which nucleic acid molecule the claim refers, or whether this nucleic acid molecule is, or is not, the DNA insert; nevertheless, because there are a plurality of polypeptides *of* the amino acid sequence set forth in SEQ ID NO: 5, it is not apparent that the nucleic acid molecule necessarily encodes a polypeptide comprising the amino acid

[6] A "nucleotide sequence" of SEQ ID NO: 4 is interpreted to mean any two or more contiguous

sequence of SEQ ID NO: 5, as it may instead comprise any portion thereof. Finally, because the DNA insert to which the claim is directed comprises a plurality of nucleotide sequences, and the claim is directed to a polypeptide encoded by a nucleic acid molecule comprising a nucleotide sequence of the DNA insert, it is presumed that the claim encompasses a plurality of structurally and/or functionally disparate polypeptides encoded by the any of such different species of nucleic acid molecules. Thus, claim 16 encompasses polypeptides comprising mere portions of the amino acid sequence of SEQ ID NO: 5. The polypeptide comprising the amino acid sequence of SEQ ID NO: 5 is not reasonably considered representative of the claimed genus of such structurally and/or functionally disparate polypeptides.

Insofar as claim 16 is directed, in the alternative, to *any* polypeptide encoded by a nucleic acid molecule comprising a nucleic acid sequence encoding a polypeptide having the amino acid sequence as set forth in SEQ ID NO: 5, the claimed polypeptide need not comprise the recited amino acid sequence. Inasmuch as there are a plurality of nucleic acid molecules comprising a nucleotide sequence encoding a polypeptide having the amino acid sequence as set forth in SEQ ID NO: 5, the claims are directed to a plurality of polypeptides. The nucleic acid molecule encoding the claimed polypeptide, i.e., a nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide having the amino acid sequence as set forth in SEQ ID NO: 5 does not necessarily encode such a polypeptide; it may encode another polypeptide, which may or may not the amino acid sequence of SEQ ID NO: 5, but might instead comprise the amino acid sequence encoded by a different reading frame, or perhaps a polypeptide comprising only a portion of the amino acid sequence of SEQ ID NO: 5. Accordingly, were the claims properly given the broadest, reasonable interpretation that is both consistent with the specification, as well as that which would be understood by the artisan, the polypeptide comprising the amino acid sequence of SEQ ID NO: 5 should not be reasonably considered representative of the claimed genus of such structurally and/or functionally disparate polypeptides.

Claim 61 is drawn to a polypeptide encoded by a nucleic acid molecule encoding a polypeptide of the amino acid sequence set forth in SEQ ID NO: 5. However, the claimed

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nucleotides of SEQ ID NO: 4.

polypeptide need not *consist of* an amino acid sequence of SEQ ID NO: 5[7]; and moreover, the claimed polypeptide does not necessarily comprise SEQ ID NO: 5, though it must be encoded by a nucleic acid molecule comprising a nucleotide sequence of a region of the nucleotide sequence of SEQ ID NO: 4 or alternatively a DNA insert encoding a "Secs-1 polypeptide". The portion of the nucleic acid molecule comprising a nucleotide sequence of a region of the nucleotide sequence of SEQ ID NO: 4 or alternatively a DNA insert encoding a "Secs-1 polypeptide", which encoded the claimed polypeptide, is not necessarily the portion comprising a nucleotide sequence of a region of the nucleotide sequence of SEQ ID NO: 4 or alternatively a DNA insert encoding a "Secs-1 polypeptide". As such, the claimed polypeptide may comprise an amino acid sequence that is wholly different from the disclosed amino acid sequence of SEQ ID NO: 5. Furthermore, SEQ ID NO: 4 comprises a plurality of "regions" comprising a plurality of nucleic acid sequences[8]. Similarly, the DNA insert to which the claim is directed presumably comprises a plurality of "regions" comprising a plurality of nucleic acid sequences. Therefore, the claim is directed to a nucleic acid molecule comprising any 2 or more nucleotides of SEQ ID NO: 4 or the DNA insert, which presumably encode a large plurality of polypeptides having substantially varying structures and functions, and no structural or functional relationship to the disclosed polypeptide comprising SEQ ID NO: 5. So, inasmuch as the claim encompasses such a genus of structurally and/or functionally disparate polypeptides, it is submitted that the disclosed polypeptide comprising the amino acid sequence of SEQ ID NO: 5 is not representative of the claimed genus, as a whole, as its disclosure would not reasonably convey Applicant's possession of the claimed invention at the time the application was filed.

In addition, although the skilled artisan could potentially isolate polypeptides that are encompassed by the claims by identifying polypeptides having a structural feature in accordance with the claims, it is duly noted that the written description provision of 35 U.S.C § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

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[7] A polypeptide of the amino acid sequence set forth in SEQ ID NO: 5 is interpreted to mean a polypeptide comprising any two or more contiguous amino acids of SEQ ID NO: 5.

[8] Again, a "nucleotide sequence" of SEQ ID NO: 4 is interpreted to mean any two or more contiguous nucleotides of SEQ ID NO: 4.

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (CAFC 1991). See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993); *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (CAFC 1991); *University of Rochester v. G.D. Searle Co.*, 69 USPQ2d 1886 1892 (CAFC 2004).

Finally, as noted previously, Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description'' Requirement (66 FR 1099-1111, January 5, 2001; hereinafter "Guidelines") states, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Guidelines further states, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. However, because the claims encompass a genus of polypeptides, which vary both structurally and functionally, the disclosed polypeptide comprising the amino acid sequence of SEQ ID NO: 5 is not representative of the genus, as a whole. Again, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. In this instance, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; Applicant has not shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; and Applicant has not described distinguishing identifying characteristics sufficient to show that Applicant was in possession of the claimed invention at the time the application was filed.

At page 5 of the amendment Applicant has cited *Enzo Biochem, Inc., v. Gen-Probe Inc.*, remarking that Federal Circuit found that reference in the specification to a deposit in a public depository, which makes its contents accessible to the public constitutes an adequate written description of the deposited material sufficient to comply with the written description requirement.

In response, the claims are drawn to a polypeptide, not the deposited material, which appears to contain a plasmid comprising a DNA insert encoding a Secs-1 polypeptide. Were the claims drawn to the deposited material, it is agreed that said deposit, if publicly accessible, would satisfy the written description requirement.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. The rejection of claims 9, 13, 14, 16, 46, 47, 57, and 59-61 under 35 U.S.C. 102(e), as being anticipated by U.S. Patent Application Publication No. 2002/0068319 A1, is maintained.

Beginning at page 6 of the amendment filed March 29, 2007, Applicant has traversed the propriety of this rejection, arguing in brief that declaration under 37 C.F.R. § 1.131 by Anthony J. Polverino and Roland Luethy, which was filed March 29, 2007, antedates the applied reference.

For reasons explained in the detail, the declaration is deemed ineffective to overcome this rejection because the evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of U.S. Patent Application Publication No. 2002/0068319 A1 to either a constructive reduction to practice or an actual reduction to practice.

It is further noted that Applicant has argued that Ni et al. does not teach "SEQ ID NO: 6, as recited in claim 14".

In response, claim 14 is drawn to a polypeptide comprising the amino acid sequence as set forth in SEQ ID NO: 6, optionally comprising an amino-terminal methionine residue. As noted, Ni et al. teaches a polypeptide comprising the amino acid sequence of SEQ ID NO: 5. The amino acid sequence of SEQ ID NO: 5 comprises the amino acid sequence of SEQ ID NO: 6; therefore, the polypeptide disclosed by Ni et al. comprises an amino acid sequence comprising SEQ ID NO: 6.

In further response to Applicant's argument that Ni et al. fails to show certain features of Applicant's invention, it is noted that the disclosed features upon which Applicant apparently relies (i.e., the disclosure that the secreted isoform of the full-length polypeptide, which lacks the amino-terminal signal peptide, consists of the amino acid sequence of SEQ ID NO: 6) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Allowable Subject Matter

13. The following claim set, drafted by the Examiner and showing the changes that are proposed, would be considered to distinguish patentably over the art of record in this application *with the provision that Applicant furnish a supplemental declaration under 37 C.F.R. § 1.131 stating that it was recognized, prior to September 24, 1999, that the open reading frame of the depicted evidentiary sequence, initiating with the first codon encoding methionine (i.e., the sequence ATG at positions 29-31 of that sequence) encodes a polypeptide having the amino acid sequence set forth in the instant application as SEQ ID NO: 5*:

Claims 1-8. (Cancelled)

Claim 9. (Previously Presented) An isolated polypeptide having the amino acid sequence as set forth in SEQ ID NO: 5 produced by a process comprising: (a) culturing a host cell containing a vector comprising a nucleic acid having a nucleotide sequence: (i)

as set forth in SEQ ID NO. 4; (ii) of a DNA insert encoding a Secs-1 polypeptide in ATCC Deposit No. PTA-1755; or (iii) encoding a polypeptide having an the amino acid sequence as set forth in SEQ ID NO. 5; under conditions suitable to express the polypeptide; and optionally (b) isolating the polypeptide from the culture.

Claims 10-12. (Cancelled)

Claim 13. (Currently Amended) An isolated polypeptide comprising the amino acid sequence: (a) as set forth in SEQ ID NO: 5; or (b) encoded by a DNA insert encoding a Secs-1 polypeptide in ATCC Deposit No. PTA-1755, wherein the ~~nucleic acid molecule~~ DNA insert encodes a polypeptide ~~of~~ comprising the amino acid sequence set forth in SEQ ID NO: 5.

Claims 14 and 15. (Cancelled)

Claim 16. (Currently Amended) An isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 5 encoded by a nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of: (a) the nucleotide sequence as set forth in SEQ ID NO: 4; (b) the nucleotide sequence of a DNA insert encoding a Secs-1 polypeptide in ATCC Deposit No. PTA-1755, wherein the ~~nucleic acid molecule~~ DNA insert encodes a polypeptide ~~of~~ comprising the amino acid sequence set forth in SEQ ID NO: 5; or (c) a nucleotide sequence encoding a polypeptide having an the amino acid sequence as set forth in SEQ ID NO: 5.

Claims 17-45. (Cancelled)

Claim 46. (Currently Amended) An isolated fusion polypeptide comprising the polypeptide of ~~either~~ Claim 13 ~~or 14~~ fused to a heterologous amino acid sequence.

Claim 47. (Previously Presented) The isolated fusion polypeptide of Claim 46, wherein the heterologous amino acid sequence is an IgG constant domain or fragment thereof.

Claims 48-56. (Cancelled)

Claim 57. (Currently Amended) A polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 5 produced by a process comprising (a) culturing a host cell containing a vector comprising a nucleic acid molecule having a nucleotide sequence of a region of the nucleotide sequence of: (i) SEQ ID NO: 4; or (ii) a DNA insert encoding a Secs-1 polypeptide in ATCC Deposit No. PTA-1755, ~~wherein the nucleic acid molecule encodes the polypeptide which is produced, and the polypeptide having the amino acid sequence set forth in SEQ ID NO: 5;~~ under suitable conditions to express the polypeptide; and optionally (b) isolating the polypeptide from the culture.

Claim 58. (Cancelled)

Claim 59. (Previously presented) The polypeptide of either Claim 9 or 57, wherein the host cell is a eukaryotic cell.

Claim 60. (Previously presented) The polypeptide of either Claim 9 or 57, wherein the host cell is a prokaryotic cell.

Claim 61. (Currently Amended) An isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 5 encoded by a nucleic acid molecule comprising a nucleotide sequence of a region of the nucleotide sequence of: (a) SEQ ID NO: 4; or (b) a DNA insert encoding a Secs-1 polypeptide in ATCC Deposit No. PTA-1755~~, wherein the nucleic acid molecule encodes a polypeptide of the amino acid sequence set forth in SEQ ID NO: 5~~.

Claim 62. (Cancelled)

Conclusion

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure: U.S. Patent No. 6,605,592 teaches two polypeptides comprising the amino acid sequence of SEQ ID NO: 5. U.S. Patent Application Publication No. 2004/001013 teaches a polypeptide comprising the amino acid sequence of SEQ ID NO: 5. U.S. Patent Application Publication No. 2002/0160382 teaches a polypeptide comprising the amino acid sequence of SEQ ID NO: 5. U.S. Patent Application Publication No. 2003/0101002 teaches a polypeptide comprising the amino acid sequence of SEQ ID NO: 5. GenEMBL EST Database Accession No. AW351839 (01 February 2000) and GenEMBL EST Database Accession No. BE899580 (29 September 2000) each lists an EST clone comprising an open reading frame encoding an amino acid sequence comprising SEQ ID NO: 5.

Other art made of record is considered pertinent to Applicant's disclosure: Clark et al. (*Genome Res.* 2003 Oct; **13** (10): 2265-2270) teaches an isolated cDNA molecule comprising the

polynucleotide sequence identical to that of SEQ ID NO: 4, which is disclosed as encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 5, which is putatively secreted.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Primary Examiner
Art Unit 1643

slr
May 3, 2007